REMARKS

The remainder of this Reply is set forth under subheadings for the convenience of the Examiner.

Specification Amendment

In response to the Examiner's objection to the written disclosure, Applicant amended the specification to recite the elements of Claims 1, 3, 4 and 10-12. Applicant notes that it is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. See *In re Koller,* 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); accord *In re Gardner,* 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); accord *In re Wertheim,* 541 F.2d 257, 191 USPQ 90 (CCPA 1976). See also M.P.E.P. §2163.I.

This amendment introduces no new matter.

The Examiner suggested in the Advisory Action that the amendments to the specification were not supported in the Figures. Applicants have not relied on the Figures to make these amendments. Rather, these amendments to the specification include word-for-word the original claims 1, 3, 4 and 10-12. As original claims form part of the written description, and are in fact part of the specification, amendments that add this same language to, in this case the Summary of the Invention, adds no new matter.

Rejection of Claims 1-6, 10-14 and 28 Under 35 U.S.C. §102(b) over U.S. 4,820,305

The Examiner maintained his rejection of the pending claims over U.S. 4,820,305 (Harms *et al.).* The Examiner stated that FIG. 1 and FIG. 6 of Harms *et al.* show an intervertebral implant formed as a unitary body; the body having a banana-shape and a first continuous radius of curvature less than a second continuous radius of curvature. The Examiner also stated that the body of the device of Harms *et al.* has rhombus-shaped openings that are evenly spaced about the circumference of the device and that the interlinking mesh forms a "serpentine arrangement." The Examiner also stated in the Response to Argument section of the instant Office Action, that he interprets the term "unitary," as it appears in Applicant's Claim 1,

as consisting of "multiple things working together as a unit," rather than as consisting of a single piece.

The word "unitary," as employed in Applicant's specification, refers only to embodiments of the intervertebral prosthesis that are a single piece. For example, FIG. 2 depicts one embodiment of a spinal implant of the invention. As can be seen from FIG. 2, the spinal implant is a single piece. Page 6, lines 7-9 of the specification describes the embodiment of FIG. 2 as follows:

> FIG. 2 shows the implant device of the invention, designated generally as 15. In the preferred embodiment illustrated, the unitary body 15 is a cage configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure.

Similarly, page 7, lines 3 and 4, makes reference to the embodiment in FIG. 2 as a unitary cage:

> The unitary cage 15 can be placed from an anterior position (anterior interbody fusion or ALIF), or posteriorly (posterior lumbar interbody fusion or PLIF, tranforaminal interbody fusion or TLIF).

There is no reference to any embodiment of an intervertebral prosthesis in the specification that includes more than a single piece as "unitary."

Applicant has explicitly stated in the specification that the invention is directed to an improved "unitary cage" and contrasted unitary construction with prior art embodiments that included a plurality of elements. For example, as stated at page 6, lines 3-6:

> Typically a pair of elements were implanted. The elements themselves were sometimes cylindrical or tubular bodies, solid plugs or cage designs, to mention a few. The present invention is directed to an improved unitary cage and method for its installation.

Further, Applicant has explicitly described the advantages of their claimed unitary intervertebral prosthesis relative to systems that employ a plurality of components. Specifically, as stated at page 9, lines 14 through 17:

> An invention has been provided with several advantages. The unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than the previous two component systems currently in use.

Applicants are entitled to employ terminology that most suitably describes their invention, and may employ drawings to facilitate clarity in their description. Item 15 of the figures plainly shows an embodiment of Applicants' claimed intervertebral prosthesis that is of a single piece. Applicants have characterized that embodiment as "unitary." Moreover, Applicants have specifically contrasted their "unitary" intervertebral prosthesis with prior art intervertebral prostheses that are of more than a single component.

The device disclosed by Harms *et al.* includes a mesh that is wrapped around to complete a loop, and which continues to be wrapped over itself. The mesh is then held together by screws or bolts:

> In the embodiment shown in FIGS. 1 and 2 the jacket is formed by rolling up a correspondingly designed sheet material and especially sheet metal strip. The two overlapping ends are interconnected by means of a screw 14. [Column 2, lines 33-37.]

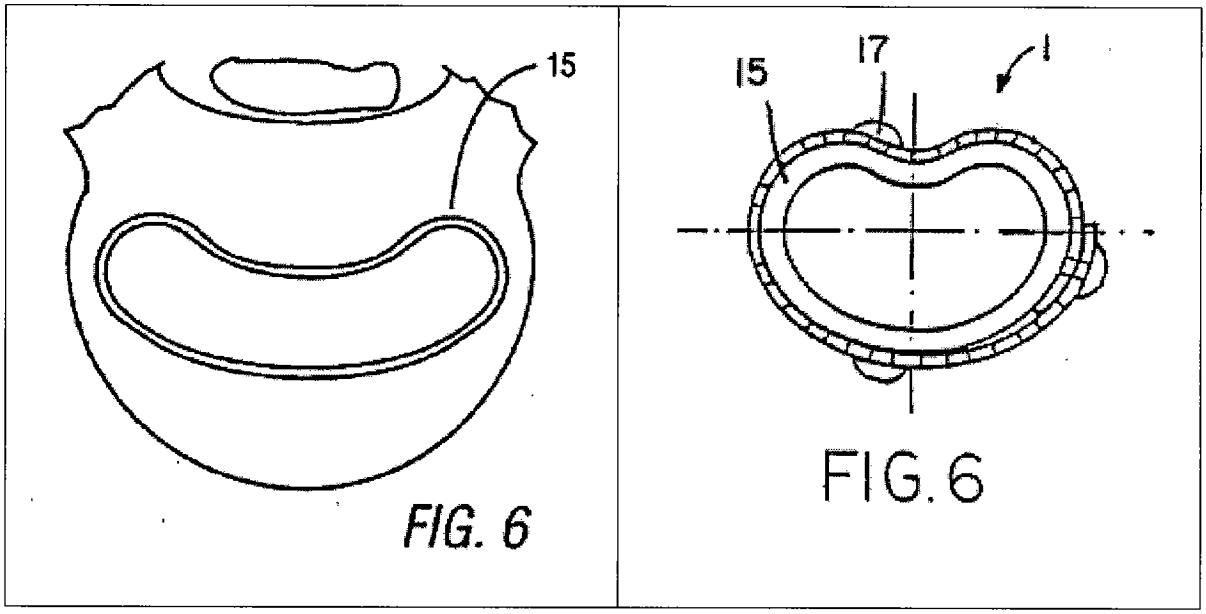
Presumably, Harms *et al.* include screws or bolts for every embodiment (see, Figs. 1, 2, 3, 4, 5, 6, 7, 8 and 9; each including screws 14 or 17 in overlapping ends) because it is necessary to keep the wrapped mesh structurally sound under axial loading. It thus appears that the mesh of Harms *et al.* cannot be used as a unitary element – it must include "non-unitary" elements in order to perform its intended function.

Applicant's claimed unitary intervertebral prosthesis is not anticipated by the intervertebral implant described by Harms *et al.* There is no disclosure or suggestion in Harms *et al.* of an intervertebral prosthesis that is unitary, as that term is employed by Applicant. Therefore, Applicant's claimed unitary intervertebral prosthesis meets the requirements of 35 U.S.C. §102(b) in view of Harms *et al.*

In addition, Harms *et al.* does not disclose, teach or suggest an intervertebral prosthesis that is banana-shaped when viewed from above. The Examiner points to Figure 6 of Harms *et al.*, however, that Figure is expressly described as a differing shape:

> For connection of vertebrae/body in the lumbal region the member preferably comprises a kidney-shaped cross-section shown in Fig. 6 or an oval cross-section shown in Fig. 7. [Column 3, lines 22-25.]

A comparison of Figure 6 of the present application to Figure 6 of Harms *et al.* Shows the difference between Applicants' banana-shape versus the kidney-shape of Harms *et al.*:



It is readily apparent that, consistent with the definition of "banana-shaped" – Applicants' shape is elongate and curved, while the Harms *et al.* shape – "kidney-shaped" – is much fatter and will fit within the intervertebral space in a very different way.

Applicants have further defined the banana-shape of the claims by reciting dimensions in the claims that are impossible for the device of Figure 6 of Harms *et al.* to achieve. For example, claim 24 recites a width of 24 to 28 mm, while claim 25, which depends from claim 24, further recites that a length of 8 to 10 mm. Harms *et al.* Figure 6, which is almost as long as it is wide, cannot possibly meet these dimensions – it is not banana-shaped. Further, Applicants have added the width to length ratio of these preferred dimension (a ratio of width to length of at least 2.4 to 1) in claim 30. Again, Harms *et al.* Figure 6 cannot meet this recitation as it is not banana-shaped.

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims Under 35 U.S.C. §103

Claims 15-27 stand rejected under 35 U.S.C. § 103(a) as being obvious variously in view of Harms *et al.,* Dove *et al.,* , U.S. 6,302,914 (Michelson), U.S. 5,062,850 (McMillan *et al.),* U.S. 6,245,108 (Biscup), U.S. 6,231,615 (Preissman) and U.S. 6,302,914 (McKay), either separately or in some combination. Regarding Claims 15-20, the Examiner stated that it would have been obvious to use alternative materials as taught by Dove *et al.* for the implant of Harms *et al.* As applied to Claims 24-26, the Examiner stated that it would have been obvious to use an implant with a width falling within the range of 24-28 mm, a height of about 10-16 mm and a length of about 10 mm, as taught by Michelson for the implant of Harms *et al.* With regard to Claim 21, the Examiner stated that it would have been obvious to use polyglycolic acid as the implant material as taught by MacMillan *et al.* for the vertebral implant of Harms *et al.* as modified by Dove *et al.* such that it degrades slowly to provide space for bone ingrowth. Concerning Claims 19 and 22, the Examiner stated that one skilled in the art would have considered it obvious to use the polymethylmethacrylate as the implant material as taught by Biscup for the vertebral implant of Harms *et al.* such that it is accepted by the patient's body and does not adversely cause irritation. The Examiner further stated that, regarding Claims 19, 22 and 23, it would be obvious to inject polymethylmethacrylate with an antibiotic as taught by Preissman with the vertebral implant of Harms *et al.* such that it enhances the treatment given to the patient to reduce infection and provides an efficient way to deliver a cement and antibiotic to a treatment site. With respect to Claim 27, the Examiner stated that it would have been obvious to use a thickness for the arc of the implant of "about 1.5 mm" as taught by McKay for the implant of Harms *et al.* as modified by Michelson such that it provides a durable support for the vertebrae that can withstand compressible loads.

None of the cited references, taken separately or in combination, remedy the deficiencies of Harms *et al.* as applied to independent Claim 1, as amended. Specifically, none of the references, taken separately or in combination, disclose or suggest an intervertebral prosthesis that includes a banana-shaped unitary body defining openings that form a serpentine arrangement of an interlinking mesh, as in Applicant's claimed invention of amended Claim 1. Therefore, Applicant's invention is not obvious in view of the cited references, taken either separately or in combination, and meets the requirements of 35 U.S.C. §103(a).

Further, and specifically as regards the rejection of claims 24 to 26, which recite dimensions of the prosthesis, the Michelson reference relied upon by the Examiner expressly describes different dimensions that result in a different shape from that recited by Applicants.

Michelson expressly states that:

> The size of the implant 100 is substantially the same size as the disc material that it is replacing . . . . In the preferred embodiment in regard to the lumbar spine the implant 100 is approximately 28-48 mm wide, approximately 36 mm being preferred. . . . The depth would at its maximum range from 20 to 34 mm with 26 to 32 being the preferred maximum depth. [Column 7, lines 40-52.]

These dimensions are expressly different than those recited by Applicants as Michelson is meant to fit within the spine differently. Michelson wants his prosthesis to be substantially the same size as the disc that it is replacing – as is clear from Applicants' Figure 6 above, Applicants' prosthesis is much smaller than the disc. Further, Applicants' banana-shaped prosthesis is much narrower. The length of Applicants' prosthesis is preferably about 8 to 10 mm, while Michelson's depth (the dimension that corresponds to Applicants' length) is said to be 20 to 34 mm – two to more than three times larger than Applicants'.

These large differences in dimension are not merely the result of picking and choosing an appropriate range – according to the present application:

> The unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than the previous two component systems currently in use. The curvature of the cage of the invention mirrors the natural curvature of the anterior and posterior curves of the vertebral bodies. It can be placed from either the anterior position or posterolateral position after standard discectomy. [Paragraph 50.]

The shape of Applicants' prosthesis, and its corresponding dimensions (a shape and dimensions that are not disclosed, taught or suggested in either Harms *et al.* or Michelson, alone or combined), achieve these results, results that are different from and better than those obtained in the art. The Examiner has not found these features in the art, nor has the Examiner provided any motivation for a person of ordinary skill in the art to provide them. Accordingly, no *prima facie* obviousness rejection has been made out.

Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above, Applicants believe that each of the presently pending claims in this application is in immediate condition for allowance and Applicants urge the Examiner to move this case to issuance.

In the event that a petition for an extension of time is required to be submitted at this time, Applicant hereby petitions under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 101896-706.

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Respectfully submitted,

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